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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,662	03/15/2001	Steven Stice	235.0032 0101	5744

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EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,662

Applicant(s)

STICE, STEVEN

Examiner

Deborah Crouch

Art Unit

1638²

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-196 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-196 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 7-24, 27-31, 33-45, 47-49, 53-69, 72-105, 108-122 and 126-156, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a metaphase donor cell is introduced into a metaphase I oocyte and the oocyte or NT embryo is naturally activated, classified in class 800, subclass 24.
- II. Claims 1-3, 7-23, 25-31, 33-45, 47-49, 53-68, 70-104 and 106-119, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a metaphase donor cell is introduced into a metaphase I oocyte and the oocyte or NT embryo is artificially activated, classified in class 800, subclass 24.
- III. Claims 1, 4, 5, 7-24, 27-31, 33-45, 47, 53-69, 72-83, 120, 123, 124 and 126-177, 180-196, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a G1 or proliferating cell is introduced into a metaphase I oocyte and the oocyte or NT embryo is naturally activated, classified in class 800, subclass 24.
- IV. Claims 1, 4, 5, 7-23, 25-31, 33-45, 47, 50, 51, 53-68, 70-83, 157-176 and 178-196, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a G1 or proliferating cell is introduced into a metaphase I oocyte and the oocyte or NT embryo is artificially activated, classified in class 800, subclass 24.
- V. Claims 1, 6-24, 27-31, 33-45, 47, 52-69, 72-83, 120 and 125-156, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a quiescent cell is introduced into a metaphase I oocyte and the oocyte or NT embryo is naturally activated, classified in class 800, subclass 24.
- VI. Claims 1, 6-23, 25-31, 33-45, 47, 52-68 and 70-83, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a quiescent

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cell is introduced into a metaphase I oocyte and the oocyte or NT embryo is artificially activated, classified in class 800, subclass 24.

- VII. Claims 30, 32, 44, 46-49, 53-65, 68, 69, 72-101, 104, 105, 108-122, 126-140, and 143-156, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a metaphase donor cell is introduced into a metaphase II oocyte and the oocyte or NT embryo is naturally activated, classified in class 800, subclass 24.
- VIII. Claims 30, 32, 44, 46, 47, 49, 53-65, 68, 70-101, 104 and 106-119, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a metaphase donor cell is introduced into a metaphase II oocyte and the oocyte or NT embryo is artificially activated, classified in class 800, subclass 24.
- IX. Claims 30, 32, 44, 46, 47, 50, 51, 53-65, 68, 69, 72-83, 120, 123, 124, 126-140, 143-173, 176, 177 and 180-196 drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a G1 or proliferating cell is introduced into a metaphase II oocyte and the oocyte or NT embryo is naturally activated, classified in class 800, subclass 24.
- X. Claims 30, 32, 44, 46, 47, 50, 51, 53-65, 68-83, 157-173, 176 and 178-196, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a G1 or proliferating cell is introduced into a metaphase II oocyte and the oocyte or NT embryo is artificially activated, classified in class 800, subclass 24.
- XI. Claims 30, 32, 44, 46, 47, 52-65, 68, 69, 72-83, 120, 125-140 and 143-156, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a quiescent cell is introduced into a metaphase II oocyte and the oocyte or NT embryo is naturally activated, classified in class 800, subclass 24.

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- XII. Claims 30, 32, 44, 46, 47, 52-65, 68 and 70-83, drawn to methods of producing a cloned nonhuman mammal and mammals, where donor genetic material from a quiescent cell is introduced into a metaphase II oocyte and the oocyte or NT embryo is artificially activated, classified in class 800, subclass 24.

The inventions are distinct, each from the other because:

Inventions I-VI and VII-XII are mutually exclusive and independent methods of producing a cloned nonhuman mammalian NT embryo, a cloned pig NT embryo, a cloned nonhuman mammal, cloned pig and a cloned cow NT embryo. The methods of inventions I-VI requires that the recipient oocyte be enucleated in the MI phase, whereas the methods of invention VII-XII requires that the recipient oocyte be enucleated in the MII phase. The protocols for nuclear transfer using MI and MII oocytes in nuclear transfer are materially different. Further the methods using an MI oocyte are not needed for the method using an MII oocyte, and vice versa.

Inventions I, III, V, VII, IX and XI and inventions II, IV, VI, VIII, X and XII are mutually exclusive and independent inventions methods of producing a cloned nonhuman mammalian NT embryo, a cloned pig NT embryo, a cloned nonhuman mammal, cloned pig and a cloned cow NT embryo. Inventions I, III, V, VII, IX and XI require natural activation of the oocyte or embryo. Inventions II, IV, VI, VIII, X and XII require artificial activation of the oocyte or embryo. The protocols for naturally and artificial activation of oocytes are materially different and separate. Further neither protocol for activation is needed for the implementation of the other protocol for activation.

Inventions I, II, VII and VIII, Inventions III, IV, IX and X, and Inventions V, VI, XI and XII are independent inventions of methods of producing a cloned nonhuman mammalian NT embryo, a cloned pig NT embryo, a cloned nonhuman mammal, cloned pig and a cloned cow NT embryo. Each of inventions I, II, VII and VIII, inventions III, IV, IX and X, and inventions V, VI, XI and XII require that the nucleus

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donor cell be from a cell in a materially different and separate stage of the cell cycle. These stages of the cell cycle have materially different and separate biochemical and biophysical properties that are a consideration for nuclear transfer. Further, none of inventions I, II, VII and VIII, inventions III, IV, IX and X, and inventions V, VI, XI and XII are required for the implementation of any other set of inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Deborah Reynolds, whose telephone number is (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Ms. Pauline Farrier, whose telephone number is (703) 305-3550.

The fax number is (703) 308-4242.

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/630

Dr. D. Crouch
June 2, 2002